

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen Williams,
Magistrate Judge

**DEFENDANTS' RESPONSES AND OBJECTIONS TO PLAINTIFFS'
NOTICE TO TAKE VIDEOTAPEDE ORAL DEPOSITION OF
JOHN FLACK, MD, MPH, FAHA, MACP, FASH**

Defendants, through their counsel of record, respond and object to Plaintiffs' Notice to Take Videotaped Deposition ("Notice") of John Flack, MD, MPH, FAHA, MACP, FASH and the document requests set forth in Exhibit A to Plaintiffs' Notice as follows:

GENERAL OBJECTIONS

1. Defendants object to the Notice as duplicative to the extent it seeks documents or information previously produced to Plaintiffs' counsel in connection with the Amended Notice to Take Videotaped Oral Deposition of John M. Flack, M.D., filed on September 20, 2021 (ECF No. 1572). Defendants refer to said material produced on September 26, 2021.

2. Defendants object to the Notice to the extent it seeks to increase or otherwise modify the burdens and obligations created by the Federal Rules of Civil Procedure.

3. Defendants object to the Notice to the extent it seeks documents or information protected by the attorney-client privilege, the attorney work product doctrine, patient confidentiality, or any other applicable immunity or privilege. Inadvertent revelation of any protected information or documents will not constitute a waiver of any privilege or any other ground for objection to discovery of the protected information and will not waive the right of

Defendants to object to the use of the information or documents during any proceeding in this action.

4. Defendants object to the Notice to the extent it seeks information and/or documents that are not reasonably calculated to lead to the discovery of admissible evidence and/or are not proportional to the needs of this case as required by Fed. R. Civ. P. 26.

5. Defendants object to the Notice to the extent it seeks or purports to seek documents that are in the possession of other parties/entities or in the public domain. To the extent that Plaintiffs are seeking documents which are readily available from other sources, Defendants object to such requests as unduly burdensome. Specifically but without limitation, to the extent Dr. Flack's list of materials considered includes deposition transcripts and exhibits for depositions taken in this litigation, Defendants decline to reproduce copies of all transcripts and deposition exhibits, which are available to all parties.

6. Defendants object to the Notice to the extent it seeks confidential documents or information of persons or entities who are not parties to this action and/or that is protected from disclosure pursuant to the patient/physician privilege relationship and/or federal or state authority and regulatory law including, without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. § 164.500, et seq.

7. In producing Dr. Flack for deposition pursuant to the Notice, Defendants do not waive the right to challenge the relevancy, materiality, and admissibility of the information sought or documents provided or to object to the use of any materials provided in any subsequent proceedings or trials.

SPECIFIC RESPONSES AND OBJECTIONS

Subject to and without waiving the foregoing General Objections, which are hereby specifically incorporated into each of the following responses as if set forth verbatim therein, Defendants respond to each individually numbered request in Exhibit A as follows:

OBJECTIONS TO DOCUMENT REQUESTS

1. *Copies of all invoices for work performed in connection with any consultation or expert work performed for or on behalf of any defendant or their counsel with regard to any issues in this MDL, including but not limited to for the review of documents, review and consultation with regard to plaintiff experts, preparation of the expert's report, and preparation for deposition or trial.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants will produce Dr. Flack's invoice(s) since the date of his prior deposition in this litigation, on September 28, 2021. Further, Defendants included information regarding Dr. Flack's hourly rates within his expert report.

2. *Any notes, i.e. written or electronic, reflecting consulting or litigation work that has not been documented in invoices.*

Defendants object to this Request as vague, overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being

beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions. Defendants further object to this Request to the extent that it seeks information prepared in anticipation of litigation, is protected by the work product doctrine, the trial preparation immunity doctrine, and the attorney-client privilege.

3. *All documents relating to any remuneration you have received from any manufacturer, distributor, or retailer of pharmaceutical drugs.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce Dr. Flack's invoices since his prior deposition on September 28, 2021. Further, Defendants included information regarding Dr. Flack's hourly rates within his expert report.

4. *Any articles, presentations, seminars, classes, or other similar documents (including PowerPoint-type slides) authored or used by Mr. Flack relating to regulatory inspections, audits, cGMP compliance, USP monographs, the Orange Book, RLDs, NDAs, ANDAs, DMF, hypertension, treatments for hypertension, ARBs, adulteration, and misbranding of drug products.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required

of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

5. *Any articles, presentations, seminars, training course, classes or other similar documents (including PowerPoint-type slides) authored by Mr. Flack and any aspect of FDA regulatory compliance for pharmaceutical drugs, including but not limited to cGMP compliance.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

6. *Copies of any documents or articles relied upon for the opinions set forth in the report served, if not listed in the report.*

Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

7. *Copies of any documents or articles reviewed in connection with the report served, whether or not listed in the report or attachments thereto.*

Defendants object to this Request as vague, overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

8. *Copies of all Publications and Presentations listed in Mr. Flack's CV, and any updated CV or testimony list.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the

expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

9. *Any illustrations, PowerPoints, images, charts, tables or demonstrative exhibits that may be used by or with Mr. Flack in connection with a Daubert hearing or trial testimony in this litigation.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions. Defendants further object to this Request as premature as no *Daubert* hearing with respect to Dr. Flack or trial has yet been set with respect to the report at issue.

10. *Documentation of any prior work Mr. Flack has done as a consultant for any of the Defendants in this action.*

Defendants object to this Request as vague, overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not

considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

11. *All documents reflecting valsartan or any other drug recalls relating to nitrosamines that you received, reviewed, or sent.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

12. *Any documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug, outside of information provided by counsel who retained the witness.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

13. *Any communications from the witness to any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug, outside of communications to counsel who retained the witness.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

14. *Any textbook referenced by the witness in forming his opinions.*

Defendants object to this Request as vague to the extent it seeks information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials

that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Subject to and without waiving these objections and any of the foregoing General Objections, Defendants produce a copy of all electronically-available documents identified on Dr. Flack's Amended List of Materials Considered, to the extent not previously provided in response to ECF No. 1572.

15. *All documents relating to any pharmacy benefit on you consulted, including identity of entities and persons with whom you consulted.*

Defendants object to this Request as vague, overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

16. *Copies of all transcripts of testimony under oath given by Mr. Flack in the last 10 years.*

Defendants object to this Request as overly broad, unduly burdensome, not reasonably limited in time or scope, and seeking information that is beyond the scope of discovery required of experts pursuant to Fed. R. Civ. P. 26. Defendants object to this Request as being beyond the scope of discovery required to be produced under Rule 26 of the Federal Rules of Civil Procedure. Rule 26(a)(2)(B) does not require an expert to produce materials that were not considered by the expert in forming the expert's opinions and will not be used to summarize or support the expert's opinions.

Dated: January 30, 2023

Respectfully submitted,

On Behalf of the Defense Executive Committee

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of January 2023, I caused a true and correct copy of the foregoing Defendants' Responses and Objections to Notice to Take Videotaped Deposition of John Flack to be filed with the Court's ECF system and served upon counsel of record. I further certify that a copy of the foregoing was served on the following by e-mail on January 30, 2023:

Plaintiffs' Executive Committee (via email)
Defendants' Executive Committee (via email)

/s/ Victoria J. Langton _____

Victoria J. Langton
Greenberg Traurig, LLP